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PRODUCT: HEALIX ADVANCE KNOTLESS BR ANCHOR (6.5mm)
SUBMISSION DATE: June 27, 2013
SUBMISSION TYPE: SPECIAL

510(k) SUMMARY

JUL 2 5 2013

Submitter:

DePuy Mitek
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

Contact Person

Kristine Christo
Manager, Regulatory Affairs
DePuy Mitek
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Raynham, MA 02767, USA

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Date Prepared

June 27, 2013

Name of Medical Device

Proprietary Name: HEALIX ADVANCE KNOTLESS BR ANCHOR (6.5mm)

Classification Name: Fastener, Fixation, Biodegradable, Soft tissue

Common Name: Bone Anchor

Substantial Equivalence

The HEALIX ADVANCE KNOTLESS BR ANCHOR (6.5mm) is substantially equivalent to:

- K130917 Mitek Healix Advance Knotless BR Anchor (4.75 and 5.5mm)

Device Classification

Single/multiple component metallic bone fixation appliances and accessories, classified as a Class II device, regulated under 21 CFR 888.3030, product code MAI.

Device Description

The proposed Healix Advance Knotless Anchor is a one piece implantable cannulated, threaded anchor designed to secure soft tissue to bone. The anchor is provided loaded on a disposable inserter driver device. The proposed anchors will be offered in a 6.5 mm size. The proposed 6.5 mm Healix Advance Knotless BR Anchor is manufactured from "biocryl rapide" material.

Indications for Use

The Healix Advance Knotless Anchors are indicated for use in the following procedures for reattachment of soft tissue to bone:

Shoulder

- Rotator Cuff
- Biceps Tenodesis

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Comparison of Technological Characteristics	The proposed Healix Advance Knotless BR Anchors will have the same design as compared to the predicate devices (4.75mm and 5.5mm) but will be larger in size (6.5mm). Both the proposed and predicate Healix Advance Knotless BR Anchors are molded from the same BR "biocryl rapide" material. No new technological characteristics were introduces as a result of the proposed changes.
Safety and Performance	**Non-clinical Testing** Product Design Verification and Design Validation activities, such as, Insertion Torque, Torque to Failure and Anchor Pullout were performed on the proposed implant device. Results of performance and safety testing have demonstrated that the proposed device is substantially equivalent to the predicate devices. Based on the indications for use, technological characteristics, and comparison to predicate devices, the proposed 6.5mm Healix Advance Knotless Anchors have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DePuy Mitek, Incorporated
% Ms. Kristine Christo
Manager, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

July 25, 2013

Re: K131974
Trade/Device Name: Healix Advance Knotless BR Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: June 27, 2013
Received: June 28, 2013

Dear Ms. Christo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131974

Device Names: Healix Advance Knotless BR Anchor

Indications for Use: The Healix Advance Knotless Anchors are indicated for use in the following procedures for reattachment of soft tissue to bone:

Shoulder

- Rotator Cuff
- Biceps Tenodesis

Prescription Use √ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices